REMARKS

Claims 1-10 are pending in the instant application. Claims 5-10 have been withdrawn from consideration by the Examiner. However, it has been acknowledged by the Examiner that upon allowance of the instant claimed precursor cells, claims 5-10 will be subject to rejoinder with claim 1-4. Accordingly, Applicants reserve the right to rejoin claims 5-10 upon allowance of the claimed precursor cells. Claims 1-4 have been rejected. Claim 1 has been amended. Support for this amendment is provided in the specification at page 8 and Examples 3 and 4. Reconsideration is respectfully requested in light of the amendments and the following remarks.

I. Rejection of Claims 1-4 under 35 U.S.C. 112, first paragraph - Lack of Enablement

The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement has been maintained. The Examiner suggests that "the claimed cells are not in accord with the observations of the working examples and the teachings of the prior art."

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's characterization of Lodie et al. (Tissue

Engineering 8:739-751;2002) as a prior art reference with respect to the instant invention. Further, Applicants respectfully disagree with the Examiner's characterization of the teachings of this references as well as its alleged relevance to the instant claimed invention.

The priority date of the instant application is January 23, 2002. Lodie et al. was published in the October 2002 issue of Tissue Engineering. Thus, Lodie et al. is not a prior art reference with respect to the instant invention.

Further, teachings of Lodie et al. relate to **adult** human bone marrow derived stem cells. In contrast, claim 1 of the instant application is drawn to a population of mammalian astrocyte restricted precursor cells being isolated from mammalian embryonic or fetal tissue, mammalian embryonic stem (ES) cell cultures or glial restricted precursor cells. Accordingly, whether or not CD44 expression is variable in adult human bone marrow derived stem cells is irrelevant to the instant claimed invention.

Applicants also respectfully disagree with the Examiner's characterization of Applicants arguments that "pp. 8-9 of the specification describe various methods for isolating the claimed astrocyte precursors cells", the Examiner's characterization of teachings at this section of

the specification, and the clearly erroneous suggestions by the Examiner that "possession of such a population [of astrocyte precursor cells that are at once A2B5 negative and CD44 positive] at the time of the invention by Applicants cannot be demonstrated."

Contrary to the Examiner's suggestion, possession of a population of astrocyte precursor cells that are at once A2B5 negative and CD44 positive at the time of the invention by Applicants is clearly demonstrated by data presented in Table 1 at page 7 of the instant application.

Further, Applicants did not simply direct the Examiner to teachings at pages 8-9 of the specification for a description of various methods for isolating the claimed astrocyte precursors cells, but rather to teachings beginning at page 8, line 31 of the instant specification and ending at page 11, line 12. Contrary to the Examiner's suggestion, this section is not only directed to isolation of CD44 positive cells from mammalian neural tube at a stage after astrocyte development, but also to isolation from neural tubes dissociated at any stage after neural tube closure, for example E8.5 in mouse, E10.5 in rat, and week 5 gestation in human (see page 9, lines 22-28), human fetal tissue derived neural cells as a source for mammalian

astrocyte restricted precursor cells (see page 10, lines 6 through 14), and use of human embryonic stem cells as source of the astrocyte restricted cells lines (see page 10, line 15 though page 11, line 12).

Accordingly, Applicants respectfully disagree with the Examiner that the skilled artisan, upon reading the entire specification, would "merely conclude that neuroepithelial precursor cells can differentiate into astrocytes, oligodendrocytes or other neural cells depending on culture conditions, and that any intermediate cell population of the final product (astrocytes) was not purified as a pure homogeneous population of astrocyte restricted cells at the time of the instant invention by Applicants." Upon reading the entire specification, the skilled artisan would conclude based upon Table 1 at page 7 that Applicants in fact purified and characterized astrocyte restricted precursor cells. Further, the skilled artisan would find sufficient guidance in teachings at pages 8-11 to make the instant claimed cells and sufficient guidance at pages 12-15 to use the instant claimed invention.

It is only the Examiner who has characterized Examples 1-5 as "working examples" not Applicants and has improperly concluded that the disclosure is not enabling based on an

analysis of only this factor while ignoring one or more of the others. See MPEP 2164.01(a)

Finally, Applicants did not submit Liu et al. as evidence of what was known at the time of filing. Instead, Applicants submitted this publication in lieu of an inventor Declaration as this peer-reviewed journal article contains evidence confirming that CD44 identifies an astrocyte restricted precursor cell that is committed to generating astrocytes (see Abstract of Liu et al.). Further, while the Examiner is correct that Liu et al. describes a transgenic mouse model, this reference also shows that CD44+ astrocyte restricted precursor cells are present in the developing rodent spinal cord before the acquisition of GFAP immunoreactivity (see page 34 of Liu et al.) and in human fetal tissue (see page 43 of Liu et al.).

MPEP 2164.01(b) and the case law are clear; as long as the specification discloses at least one method of making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims, then the enablement requirement of 35 U.S.C. 112, first paragraph, is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The instant specification, which show possession of the claim invention at page 7, provides

multiple methods for making the invention at pages 8-11 and multiple uses at pages 8-12 clearly meets this requirement.

Withdrawal of this rejection is therefore respectfully requested.

II. Rejection of Claims 1-4 under 35 U.S.C. 102(e)

The rejection of claims 1-4 under 35 U.S.C. 102(e) as being anticipated by Carpenter (U.S. Patent 6,833,269) has been maintained.

Applicants respectfully traverse this rejection.

Claims of the instant application have been amended to recite that the astrocyte-restricted precursor cells generate astrocytes but not oligodendrocytes under oligodendrocyte differentiation conditions of plating in a bFGF-containing medium for 2 days and then switching to a medium containing PDGF or exposure to PDGF and thyroid hormone. Support for this amendment is provided in teachings at page 8 and Examples 3 and 4 of the instant specification.

Carpenter does not teach astrocyte-restricted precursor cells which generate astrocytes but not oligodendrocytes under oligodendrocyte differentiation conditions of plating in a bFGF-containing medium for 2 days and then switching to a medium containing PDGF or exposure to PDGF and thyroid

hormone. Instead, cells of Carpenter cultured in a cocktail containing both bFGF and PDGF generated oligodendrocytes, astrocytes and neurons. See Examples 1 through 3 of Carpenter.

Nor does it necessarily flow from teachings of Carpenter that a homogeneous cell population which is CD44+ can be isolated from embryonic stem cells which will generate astrocytes but not oligodendrocytes even when cultured under conditions known to generate oligodendrocytes in other precursor cell populations. Instead, Carpenter arguably teaches away from such a cell population since their A2B5 positive cells generated oligodendrocytes, astrocytes and neurons (see Example 3 of Carpenter). Accordingly, the instant claimed invention is also not inherent in teachings of Carpenter. See MPEP 2112.

MPEP 2131 is clear; a claim is anticipated only if each and every element as set forth in the claims is found either expressly or inherently described in a single prior art reference. Accordingly, since all the elements of the instant claimed invention are not expressly or inherently described in Carpenter, this reference cannot anticipate the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. 102(e) is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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